

PUBLIC LAW 95-622—NOV. 9, 1978

COMMUNITY MENTAL HEALTH  
CENTERS ACT, AMENDMENTS

39-139 O - 78 (545)

92 STAT. 3412

PUBLIC LAW 95-622—NOV. 9, 1978

Public Law 95-622  
95th Congress

An Act

Nov. 9, 1978  
[S. 2450]

To amend the Community Mental Health Centers Act to revise and extend the programs under that Act, to amend the Public Health Service Act to revise and extend the programs of assistance for libraries of medicine, the programs of the National Heart, Lung, and Blood Institute, and of the National Cancer Institute, and the program for National Research Service Awards, to establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

Community  
Mental Health  
Centers Act,  
amendments.  
Community  
Mental Health  
Centers  
Extension Act of  
1978.

TITLE I—COMMUNITY MENTAL HEALTH CENTERS  
EXTENSION

SHORT TITLE; REFERENCE TO ACT

42 USC 2689  
note.

SEC. 101. (a) This title may be cited as the "Community Mental Health Centers Extension Act of 1978".

(b) Whenever in this title (other than in sections 109 and 110(d)) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Community Mental Health Centers Act.

42 USC 2689  
note.

EXTENSIONS OF AUTHORIZATIONS

42 USC 2689a.

SEC. 102. (a) Section 202(d) is amended by striking out "and" after "1977," and inserting before the period a comma and the following: "\$1,500,000 for the fiscal year ending September 30, 1979, and \$1,000,000 for the fiscal year ending September 30, 1980".

42 USC 2689b.

(b) (1) Section 203(d)(1) is amended by striking out "and" after "1977," and inserting before the period a comma and the following: "\$34,500,000 for the fiscal year ending September 30, 1979, and \$35,000,000 for the fiscal year ending September 30, 1980".

42 USC 2689c.

(2) Section 203(d)(2) is amended (A) by striking out "1978" and inserting in lieu thereof "1980", and (B) by striking out "two fiscal years" and inserting in lieu thereof "four fiscal years".

42 USC 2689d.

(c) Section 204(c) is amended by striking out "and" after "1977," and inserting before the period a comma and the following: "\$20,000,000 for the fiscal year ending September 30, 1979, and \$3,000,000 for the fiscal year ending September 30, 1980".

42 USC 2689g.

(d) Section 205(c) is amended by striking out "and" after "1977," and inserting before the period a comma and the following: "\$30,000,000 for the fiscal year ending September 30, 1979, and \$25,000,000 for the fiscal year ending September 30, 1980".

42 USC 2689h.

(e) Section 212(c) is amended by striking out "three" and inserting in lieu thereof "five".

42 USC 2689q.

(f) Section 213 is amended by striking out "and" after "1977," and inserting after "1978," the following: "and \$25,000,000 for the fiscal year ending September 30, 1979,".

(g) Section 231(d) is amended by striking out "and" after "1977," and inserting before the period a comma and the following:

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through (h) as paragraphs (1) through (8), respectively, and (10) by inserting "(a)" after "301." and by adding at the end the following:

"(b) (1) The Secretary shall conduct and may support through grants, grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

"(2) (A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

Low-level  
ionizing  
radiation.

"(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

"(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

"(4) The Secretary shall publish an annual report which contains—

Annual report,  
publication.

"(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

"(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

"(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

"(D) a description of (i) each request received during the year involved—

"(I) from a Federal agency outside the Department of Health, Education, and Welfare for the Secretary, or

"(II) from an entity within the Department of Health, Education, and Welfare to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of sub-

...sity days from the date of enactment, the Commission shall publish an annual report on November first of each year, to be submitted to the President and appropriate Congressional committees, which includes the President and appropriate Congressional committees, which includes:

(A) a complete list of all recommendations made to any Federal agency during the previous fiscal year;

(B) a description of subsequent administrative action taken; and

(C) a description of the reasons why an agency may have failed to take action.

The House amendment adopts the provisions of the Senate bill, with minor changes and additions. It requires that the report be on all the Commission's activities during the previous fiscal year and not limited to a discussion of the Commission's recommendations to Federal agencies. The House amendment further changes the report deadline to December 15, it being felt that one month may not allow the Commission sufficient time to prepare a thorough and competently done annual report. The report may include additional recommendations for administrative or legislative action.

#### ADMINISTRATIVE PROVISIONS

The Senate bill includes a number of provisions concerning the Commission's authority to hire staff and consultants, hold hearings, publish reports and disseminate information, determine the order in which studies are undertaken, and enter into contracts.

The House amendment adopts these provisions of the Senate bill, and adds the additional provision that the Commission may procure temporary and intermittent services of other appropriate Federal employees.

#### CONFIDENTIALITY

The Senate bill prohibits the Commission from disclosing information pertaining to trade secrets, citing the exemption from disclosure under the Freedom of Information Act (section 552(b)(4) of title V, United States Code), and information concerning "identifiable personal data", unless done under conditions which fully protect the rights of the individual. The Senate bill also prohibits the disclosure of classified information.

The House amendment adopts the first part of this provision concerning the disclosure of trade secrets, but substitutes for the remainder the prohibition to disclose information pertaining to the privacy of medical records, citing exemption of section 552(b)(6) of title V of the United States Code.

The language in the Senate bill was considered to pose some ambiguities of interpretation, particularly the definition of "identifiable personal data." However, it was believed that the intent of this provision of the Senate bill could be encompassed by prohibiting disclosure of data described in the appropriate section of the Freedom of Information Act. It was further believed that no reference to the disclosure of classified information was necessary, since by definition classified information is protected from disclosure.

#### AUTHORIZATION OF APPROPRIATIONS

The Senate bill authorizes appropriations of \$6,000,000 per year for the Commission beginning with 1979.

The House amendment adopts a so-called "sunset" provision which provides for the termination of the Commission after four years.

The House amendment adopts a provision similar to that in the Senate bill but with a drafting change to permit the Commission to complete its activities, under the authorizations provided in this bill, by December 31, 1982.

#### MISCELLANEOUS PROVISIONS

##### Initial Appointment of Members

The House amendment adds a provision not in the Senate bill requiring that the President appoint members of the Commission within ninety days of the date of enactment. Since the provision to permit present members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to serve until members of the new Commission were appointed was stricken, it was considered important to require the appointment of the new Commission as soon as possible.

##### Repeal of Existing Statutory Provisions

The Senate bill specifically repeals section 217(f) of the Public Health Service Act, which creates a National Advisory Council for the Protection of Human Subjects of Biomedical and Behavioral Research. The Senate bill also repeals sections 221 and 213 of the National Research Act.

The House amendment adopts the first provision of the Senate bill respecting repeal of section 217(f) of the Public Health Service Act. However, the provisions of sections 211 and 213 of the National Research Act have expired. Therefore, these provisions of the Senate bill are deleted.

Mr. Speaker, the substitute amendment being presented to the House for consideration today contains three provisions in addition to H.R. 12347 as reported by the committee.

The first of these requires that the Department of HEW conduct and support research and information programs in human nutrition. This is an area vitally important to human health in which research has, in recent years, received inadequate Federal support.

The second provision is more or less a technical amendment delaying the date by which the Commission on Digestive Diseases must submit its report for about 4 months.

The third provision directs the Secretary of HEW to review Federal research programs concerned with the biological effects of ionizing radiation.

For the purpose of clarifying the legislative history, I shall summarize the background effect upon existing law and intent of these amendments.

During its hearings on biomedical research and other health issues this year, the committee has repeatedly been informed about the need for increased Federal support of basic, clinical, and applied research relating to nutrition as well as other programs to disseminate the results of this research and to assure its practical application. For years public health laws have authorized nutrition programs and activities, and entities in the Department of Health, Education, and Welfare, such as the National Institutes of Health, the Food and Drug Administration, the HEW's service agencies have taken the lead in conducting activities implied in the statutory author-

ities underlying these programs and activities. The Commission on Digestive Diseases, the Institute of Medicine, and the National Commission on Nutrition and Health. Recently enacted health laws reinforce this recognition. The nutrition research information and service programs of the Department of Health, Education, and Welfare have been recognized by the Congress in recently enacted legislation as an integral part of our current inquiries and interventions into the entire spectrum of problems associated with human health and disease.

It is therefore appropriate that an amendment be included in the Public Health Service Act to provide more specific statutory direction and authority for the Secretary of Health, Education, and Welfare to assure that these programs and activities continue to be supported and augmented by the Department of HEW, to assure that they are coordinated among the appropriate entities within the Department of HEW, and to provide guidance to other departments and agencies outside of HEW respecting their comparable programs and activities. This amendment is intended to require the Secretary to strongly support these programs and activities and to renew the recognition of the Congress that he and the Department of HEW have the responsibility to protect and maintain the health of all citizens, including the responsibility for the nutritional aspects related to the prevention, diagnosis, and treatment of disease.

The amendment to delay the date for submission of the report of the Commission on Digestive Diseases is simply intended to provide the Commission with a sufficient opportunity to make further refinements in its draft report before it submits its final report to the Congress. The Commission was established by title III of the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976, Public Law 94-562, and is required by that law to submit to Congress next month a final report containing a long-range plan and recommendations for the development and organization of national resources to effectively deal with digestive diseases.

The provision directing the Secretary of HEW to review Federal research programs into the biological effects of ionizing radiation was prompted by a number of problems in radiation safety which have come to the attention of my colleague from California, Mr. Brown and myself.

Over the last 9 months the Subcommittee on Health and the Environment has conducted lengthy oversight hearings on the question of the potential health dangers of low-level ionizing radiation. We have found a growing public concern about the safety of medical and dental radiation, nuclear research and nuclear powerplants.

In investigating what we know about the effects of low-level radiation and the basis of that knowledge, the subcommittee uncovered serious problems in Federal research programs on the biological effects of ionizing radiation. Problems are spread through the Federal Government with too little emphasis on radiation research in health agencies such as the Department

Health, Education, and Welfare and the Environmental Protection Agency. In the past there has been little or no inter-agency coordination of research and no overall central direction of where our Nation's radiation research priorities ought to be placed. Some radiation research programs are of questionable management—lacking systematic effort to solicit and fund on a competitive basis the best research projects, and plagued by inadequate peer review systems and haphazard mechanisms to assure public and professional dissemination of research results.

The substitute House amendment provides a partial response to these shortcomings by directing the Secretary of Health, Education, and Welfare to bolster his department's radiation research through a comprehensive program to investigate the biological effects of ionizing radiation. This provision would move the Department into a more appropriate position as a leader in radiation research. This is only fitting given the Department's statutory mission as guardian of public health and since as much as 90 percent of the manmade ionizing radiation to which we are exposed results from medical and dental uses of radiation.

But since last winter when the bill was fashioned in subcommittee further analyses of Federal research indicates the need for a broader response to the weaknesses of current Federal radiation research efforts. What is required is a systematic, comprehensive review of each significant Federal research program funding or supporting ionizing radiation research.

I have worked with the gentleman from Kentucky, Dr. CARTER, and the gentleman from California, Mr. GEORGE BROWN, chairman of the Committee on Science and Technology, Subcommittee on Environment and the Atmosphere, to add this amendment which would direct the Secretary of Health, Education, and Welfare to undertake such a review. We would expect it to be completed within 2 years. A final report to Congress is expected not later than December 31, 1980, with an interim report by October 31, 1979.

The committee intends that in conducting the comprehensive review of Federal research programs the Secretary shall—

First, review the history of such programs;

Second, on the basis of a management review, analyze the goals and management of research conducted under such programs and the relationship of such research to the goals and mission of the Federal agencies conducting and supporting such research;

Third, on the basis of a scientific peer review, analyze the conduct and quality of such research;

Fourth, determine whether the programs are responsive to the public health and safety needs respecting ionizing radiation, including the needs of Federal agencies in the administration of programs under the Atomic Energy Act of 1946, as amended, and the Environmental Protection Act of 1970, as amended.

National Academy of Sciences and appropriate Federal agencies, the needs and direction of future Federal research programs, including the requirements for personnel and funding; and

Sixth, consider existing and potential methods to assure rapid dissemination and informed review of findings made in research conducted or supported under such Federal research program.

Each Federal agency which administers a program of research on the biological effects of ionizing radiation shall cooperate with the Secretary, and with any entity assisting the Secretary in his review, to enable the Secretary to conduct the review.

It is our intention that the Secretary conduct the independent scientific peer review and program management review of federally supported radiation research by contract with the National Academy of Sciences. This contractual relationship, of course, assumes that terms of the study, its conduct and its financing, can be agreed upon by NAS and the Secretary. If such contractual relationship cannot be arranged with the NAS, the Secretary shall enter into a similar arrangement with another appropriate public or nonprofit private entity.

The National Academy is the preferred agency to conduct the scientific peer review and the management review because of the clear need for totally independent review. The Secretary therefore must assure the contract provides for a full, independent review carried out by carefully selected personnel and conducted in such a way as to assure the integrity and balance of the report. We would expect that the House Commerce Committee and the House Science and Technology Committee will be advised and consulted by the Secretary on a regular basis during the development of the study proposal, negotiations on contract arrangements, and the conduct of the review.

In his arrangements with NAS, the Secretary would be expected to specify the departments and agencies whose research programs are to be included in the scientific and management review. It certainly is expected that the review will include all research on the biological effects of ionizing radiation within the Departments of Energy, Defense, and Health, Education, and Welfare, as well as within the Environmental Protection Agency and the Nuclear Regulatory Agency.

I salute the work of the Senate sponsors of S. 2584, "The Nuclear Regulatory Commission authorizations for fiscal year 1979", requiring an assessment of the research needs of radiation regulatory agencies. We expect the HEW/NAS review under this provision to take into consideration and critically evaluate the research needs assessment and study plan to be produced as a result of the implementation of S. 2584.

It is expected that all agencies and department's will extend full cooperation to the Secretary in his conduct of this review. This cooperation should include providing the Secretary with information on the goals, scope, organization, management, funding, and results of ionizing radiation research programs and facilitating the scientific and management reviews required under this amendment.

The provisions of this amendment do not conflict in any way with the current review the Department is coordinating in response to a White House directive of May 9, 1978. That directive charged an interagency group with recommending to the President, among other things:

A study or series of studies which would determine the effects of radiation exposure on participants in nuclear tests, including members of the armed forces and civilian personnel, workers at nuclear facilities and projects, and other persons as indicated.

The charge of that White House directive is totally separate from the actions required by the Secretary under this amendment. At this time, HEW has not been ordered to conduct a peer review or a management review. Nor could they be expected to do so in the time allotted for their report. Yet, it is clear that in the long run there is a clear need for a comprehensive peer review and management review.

Equally clear is that there is no need for the Secretary to delay his report and recommendations to the President until this scientific and management review is completed. Nor is there any need for the President to delay acting upon that report. One simply is not dependent upon the other.

Mr. Speaker, I want to take this opportunity to thank the chairman of the full committee, Mr. SPACER, for his support of this legislation. I particularly want to thank the distinguished ranking minority member of the subcommittee, Dr. CARTER for his leadership and efforts in bringing this bill to the floor of the House. Finally, I want to thank all the other members of the Subcommittee on Health and the Environment—Mr. PREYER, Mr. SCHULTZ, Mr. FLORIO, Mr. MAGUIRE, Mr. OTTINGER, Mr. MARKEY, Mr. WALGREEN, Mr. MADIGAN, and Mr. SKUBERTZ—for their support of this bill.

Mr. Speaker, I also wish to thank and commend our colleagues in the Senate: Senators KENNEDY, SCHWEICHER, WILLIAMS, NELSON, JAVITS, and the other members of the Committee on Human Resources for compromising spirit and excellent work on this legislation.

Mr. Speaker, I strongly urge you and my colleagues in the House to support this legislation for the continued authorization of biomedical research and training programs of the Medical Libraries; National Heart, Lung and Blood Institute; National Cancer Institute; and National Research Service Awards.

STATEMENT OF THE HONORABLE GEORGE B. BROWN, JR., IN SUPPORT OF AMENDMENT TO H.R. 12347

(Biomedical Research and Training Act)

One of the provisions of the substitute bill offered here today, is the result of an extensive review of research on health effects of ionizing radiation. The Subcommittee on the Environment and the Atmosphere which I chair, authorizes the budget for the Office of Environment in the Department of Health, Education, and Welfare. The primary objective of such research is to